General

Guideline Title

SeHCAT (tauroselcholic [75 selenium] acid) for the investigation of diarrhoea due to bile acid malabsorption in people with diarrhoea-predominant irritable bowel syndrome (IBS-D) or Crohn's disease without ileal resection.

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). SeHCAT (tauroselcholic [75 selenium] acid) for the investigation of diarrhoea due to bile acid malabsorption in people with diarrhoea-predominant irritable bowel syndrome (IBS-D) or Crohn's disease without ileal resection. London (UK): National Institute for Health and Care Excellence (NICE); 2012 Nov. 34 p. (Diagnostics guidance; no. 7).

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

SeHCAT (tauroselcholic [^{75}selenium] acid) is a potentially clinically important test for diagnosing bile acid malabsorption, which may be currently underdiagnosed. There is insufficient evidence to determine whether SeHCAT is a cost-effective option for diagnosing bile acid malabsorption in people with diarrhoea-predominant irritable bowel syndrome (IBS-D) and people with Crohn's disease without ileal resection. Therefore, for people with these conditions, SeHCAT is recommended for use in research to collect evidence about its clinical benefits and risks and the acceptability associated with diagnosing and treating bile acid malabsorption.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Bile acid malabsorption
- Diarrhoea-predominant irritable bowel syndrome (IBS-D)
- Crohn's disease

Guideline Category

Diagnosis

Evaluation

Technology Assessment

Clinical Specialty

Family Practice

Gastroenterology

Internal Medicine

Nuclear Medicine

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To determine the clinical and cost-effectiveness of SeHCAT (tauroselcholic [^{75}selenium] acid) in diagnosing bile acid malabsorption in people with chronic diarrhoea who have been diagnosed with irritable bowel syndrome (IBS-D) and people with Crohn's disease without ileal resection

Target Population

- People with chronic diarrhoea considered likely to have irritable bowel syndrome (IBS-D)
- People with chronic diarrhoea who have been diagnosed with Crohn's disease and have not had an ileal resection

Interventions and Practices Considered

SeHCAT (tauroselcholic [^{75} selenium] acid)

Major Outcomes Considered

- Effect of testing on treatment plan (e.g., surgical or medical management), where information on the appropriateness of the final treatment plan is also reported
- Effect of testing on clinical outcome (e.g., morbidity and adverse events)
- Prognosis – the ability of test result to predict clinical outcome (e.g., response to treatment)
- Acceptability of tests to patients or surrogate measures of acceptability (e.g., waiting time and associated anxiety)

- Adverse events associated with testing (e.g., pain/discomfort experienced during the procedure and waiting times before results)
- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an External Assessment Group to perform a systematic literature review on the technology considered in this diagnostics guidance and prepare a Diagnostics Assessment Report (DAR). The DAR for this guidance was prepared by Kleijnen Systematic Reviews Ltd. in collaboration with Erasmus University Rotterdam and Maastricht University (see the "Availability of Companion Documents" field).

Assessment of Clinical Effectiveness

Inclusion and Exclusion Criteria

Participants

Study populations eligible for inclusion will be:

All patients (including children) referred to a gastrointestinal (GI) clinic for investigation and diagnosis of bile acid malabsorption (BAM), which is a common underlying cause of chronic diarrhoea and the measurement of bile acid pool loss.

This report will focus on two specific populations:

1. People presenting with chronic diarrhoea with unknown cause and symptoms suggestive of functional disease
2. People with Crohn's disease and chronic diarrhoea with unknown cause (i.e., before resection of the terminal ileum).

Setting

The relevant setting is secondary care.

Interventions

The intervention is tauroselcholic [^{75}selenium] acid (SeHCAT).

Comparators

The comparator will be no SeHCAT test (the current situation).

Outcomes

The following outcomes are considered:

- Effect of testing on treatment plan (e.g., surgical or medical management), where information on the appropriateness of the final treatment plan is also reported
- Effect of testing on clinical outcome (e.g., morbidity and adverse events)
- Prognosis – the ability of test result to predict clinical outcome (e.g., response to treatment)

For included studies reporting any of the above outcome measures, the following outcomes will also be considered if reported:

- Acceptability of tests to patients or surrogate measures of acceptability (e.g., waiting time and associated anxiety)
- Adverse events associated with testing (e.g., pain/discomfort experienced during the procedure and waiting times before results).

Study Design

The following study designs were eligible for inclusion:

- Randomised or non-randomised controlled trials, where participants are assigned to the intervention or comparator tests, for treatment planning, and outcomes are compared at follow-up.
- Observational studies which report the results of multi-variable regression modelling with clinical outcome as the dependent variable and index test result as an independent variable. Included studies should control adequately for potential confounders (e.g., age, gender, disease, etc.).

The following study/publication types were excluded:

- Pre-clinical and animal
- Reviews, editorials, and opinion pieces
- Case reports
- Studies reporting only technical aspects of the test, or image quality
- Studies with <10 participants

Since no studies were found with either of the above mentioned study designs, it was decided to broaden the inclusion criteria by allowing lower levels of evidence (change to protocol). Therefore, observational studies reporting data to calculate the accuracy of SeHCAT in predicting treatment response and studies reporting data on the effectiveness of treatment given a positive and/or negative SeHCAT test will also be included.

Search Strategy

Search strategies were based on principal diagnosis and intervention, as recommended in the Centre for Reviews and Dissemination (CRD) guidance for undertaking reviews in health care and the Cochrane Handbook for Diagnostic Test Accuracy Reviews.

The following databases were searched for relevant studies. No date limit was used and searches were limited to remove animal studies:

- MEDLINE (1946-2012/04/wk1) (OvidSP)
- MEDLINE In-Process Citations and Daily Update (up to 2012/04/17) (OvidSP)
- EMBASE (1980-2012/wk15) (OvidSP)
- Cochrane Database of Systematic Reviews (CDSR) (Cochrane Library Issue 3:2012) (Wiley)
- Cochrane Central Register of Controlled Trials (CENTRAL) (Cochrane Library Issue 4:2012) (Wiley)
- Database of Abstracts of Reviews of Effects (DARE) (up to 2012/04/19) (CRD website)
- Health Technology Assessment Database (HTA) (up to 2012/04/19) (CRD website)
- Science Citation Index (SCI) (1970-2012/04/18) (Web of Science)
- National Institute for Health Research (NIHR) HTA (up to 2012/04/19) (Internet)

Supplementary searches were undertaken on the following resources to identify grey literature, completed and ongoing trials:

- National Institutes of Health (NIH) Clinicaltrials.gov (Internet) http://www.clinicaltrials.gov/
- Current Controlled Trials (Internet)
- World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (Internet) http://www.who.int/ictrp/en/
- European Union Clinical Trials Register (EU CTR) (Internet) https://www.clinicaltrialsregister.eu/

Original clinical effectiveness and trials searches undertaken between 9th and 16th January 2012 retrieved 5,142 records. Update searches undertaken between 17th and 20th April 2012 found an additional 82 records (after deduplification), but no new includes.

Searches were undertaken to identify studies of SeHCAT in the diagnosis of bile acid malabsorption (BAM). The main EMBASE strategy for each set of searches was independently peer reviewed by a second Information Specialist, using the PRESS-EBC checklist. Search strategies were developed specifically for each database and the keywords associated with BAM were adapted according to the configuration of each database. Searches took into account generic and other product names for the intervention. No restrictions on language or publication status were

applied. Limits were applied to remove animal studies. Full search strategies are reported in Appendix 1 in the DAR.

Electronic searches were also undertaken for conference abstracts (refer to the DAR for specific databases and web sites searched).

Identified references were downloaded in Endnote X4 software for further assessment and handling.

References in retrieved articles were checked for additional studies. The final list of included papers was also checked on PubMed for retractions and errata.

Inclusion Screening

Two reviewers independently screened the titles and abstracts of all reports identified by searches and any discrepancies were discussed and resolved by consensus. Full copies of all studies deemed potentially relevant, after discussion, were obtained and the same two reviewers independently assessed these for inclusion; any disagreements were resolved by consensus.

Assessment of Cost-effectiveness

Search Strategy

Searches were undertaken to identify cost-effectiveness studies of SeHCAT in the diagnosis of BAM and bile acid sequestrants (BAS) used to treat BAM. As with the clinical effectiveness searching, the main EMBASE strategy for each set of searches was independently peer reviewed by a second Information Specialist, using the PRESS-EBC checklist. Search strategies were developed specifically for each database and searches took into account generic and other product names for the bile acid sequestrants and SeHCAT. No restrictions on language or publication status were applied. Limits were applied to remove animal studies. Full search strategies are reported in Appendix 1 in the DAR.

The following databases were searched for relevant studies with no date limits:

- MEDLINE (1946-2012/01/wk1) (OvidSP)
- MEDLINE In-Process Citations and Daily Update (up to 2012/01/13) (OvidSP)
- EMBASE (1980-2012/wk02) (OvidSP)
- National Health Service Economic Evaluation Database (NHS EED) (up to 2012/01/16) (CRD website)
- Health Economic Evaluation Database (HEED) (Wiley) (up to 2012/03/06) http://onlinelibrary.wiley.com/book/10.1002/9780470510933
- EconLit (1886-2012/01/16)(EBSCO)
- Science Citation Index (SCI) (1970-2012/01/12) (Web of Science)

See Section 5.1 in the DAR for information on supplementary search resources.

Due to the lack of studies found that matched all the criteria, an additional keyword search of the Clinical Effectiveness Endnote Library was performed to identify potentially relevant cost/economic studies. After deduplication 121 records were identified (see Appendix 1 in the DAR).

The following additional searches were requested by the health economists as part of this process:

Searches for utility weights for BAM, irritable bowel syndrome (IBS), Crohn's & chronic diarrhoea were conducted on the Cost-Effectiveness Analysis (CEA) Registry: https://research.tufts-nemc.org/cear4/Home.aspx.

Additional searches were also requested for health-related quality of life and cost effectiveness for both Crohn's disease and IBS on the following resources:

- NHS Economic Evaluation Database (NHS EED) (CRD website)
- MEDLINE (OvidSP)

These searches were targeted to find results to inform the inputs of a model and were not intended to be used for a comprehensive systematic literature review.

The final list of included papers was also checked on PubMed for retractions and errata.

Number of Source Documents

Assessment of Clinical Effectiveness

The literature searches of bibliographic databases identified 4,240 references. After initial screening of titles and abstracts, 185 were considered to be potentially relevant and ordered for full paper screening. Five additional papers were ordered based on information from the manufacturer. One additional study was identified from searches of clinical trials registries. Of the total of 191 publications considered potentially relevant, three could not be obtained within the time scale of this assessment; two possibly because the reference details were not correct, and one was held in British Library stacks which are currently closed for asbestos removal.

Based on the searches and inclusion screening described above, 24 publications of 21 studies were included in the review. One of the included studies was reported as a conference abstract and another included study was reported as a student's project under supervision of Prof McLaughlin at the University of Manchester. See Figure 4 in the Diagnostics Assessment Report (DAR) (see the "Availability of Companion Documents" field) for the flow of studies through the review process and Appendix 5 in the DAR for all publications excluded at the full paper screening stage with reasons for exclusions.

Assessment of Cost-effectiveness

- See Figure 6 in the DAR for the flow of searches developed for tauroselcholic [^{75}selenium] acid (SeHCAT) health economics. Records retrieved 3,292 studies prior to deduplication, total of 2,975 after deduplication.
- The Assessment Group submitted a *de novo* model.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an External Assessment Group to perform a systematic literature review on the technology considered in this diagnostics guidance and prepare a Diagnostics Assessment Report (DAR). The DAR for this guidance was prepared by Kleijnen Systematic Reviews Ltd. in collaboration with Erasmus University Rotterdam and Maastricht University (see the "Availability of Companion Documents" field).

Assessment of Clinical Effectiveness

Data Extraction

Data relating to study details, participants, intervention and comparator tests, reference standard, and outcome measures were extracted by one reviewer, using a piloted, standard data extraction form. A second reviewer checked data extraction and any disagreements were resolved by consensus.

Quality Assessment

The evidence-based Quality Assessment of Diagnostic Accuracy Studies (QUADAS) tool, is recommended for assessing the methodological quality of test accuracy studies. A revised version of QUADAS (QUADAS-2) has recently been published (www.QUADAS.org). QUADAS-2 more closely resembles the approach and structure of the Cochrane risk of bias tool. It is divided into four key domains covering participant selection, index test, reference standard, and the flow of patients through the study (including timing of tests).

Each domain is rated for risk of bias (low, high, or unclear) and the tool provides signalling questions, in each domain, to aid reviewers in reaching a judgement. The participant selection, index test and reference standard domains are also separately rated for concerns regarding the applicability of the study to the review question (low, high, or unclear). Thus, QUADAS-2 separates bias from external validity (applicability) and does not include any items which only assess reporting quality. The QUADAS-2 tool does not currently include domains specific to the assessment of studies comparing multiple index tests, such as those included in this assessment. Further development of QUADAS-2 in this area is planned. A modified version of the QUADAS-2 tool, which includes an additional domain for the comparator test and additional signalling questions in the 'flow and timing' domain, has been used in this assessment. Review-specific guidance was produced for the use of the modified version of QUADAS-2 and is reported in Appendix 2 in the DAR.

The results of the quality assessment are summarised and presented in tables and graphs in the results of the systematic review (Section 4.6) and are presented in full, by study, in Appendix 3 in the DAR. No diagnostic accuracy data set included in this assessment was of sufficient size to allow statistical exploration of between study heterogeneity based on aspects of risk of bias. The findings of the quality assessment were used to inform recommendations for future research. The risk of bias in the controlled clinical trial was assessed using a table based on the Cochrane Collaboration's tool for assessing risk of bias.

The methodological quality of included effectiveness studies was assessed using standard tools. The Cochrane Collaboration quality assessment checklist was used to assess the methodological quality of each included study as detailed in Table 2 in the DAR.

Each study was awarded a 'yes', 'no' or 'unclear/unknown' rating for each individual item in the checklist. Any additional clarifications or comments were also recorded.

The quality of case-control and cohort studies was assessed using specific checklists for the methodological quality assessment of these studies. In addition, the Assessment Group used an adapted version of the quality assessment checklist by Wedlake et al. (ee Appendix 2 in the DAR).

Quality assessment was carried out independently by two reviewers. Any disagreements were resolved by consensus.

Methods of Analysis/Synthesis

Meta-analysis was considered inappropriate, due to the small number of test accuracy studies with varying diagnostic thresholds and between study heterogeneity in other study design categories (principal diagnosis, treatment dose, definition of response, follow-up period and tauroselcholic [^{75}selenium] acid [SeHCAT] administration); the Assessment Group, therefore employed a narrative synthesis. Typically, this involved the use of text and tables to summarise data. Studies were organised by clinical application (diagnosis of bile acid malabsorption [BAM] in those with chronic diarrhoea and those with Crohn's disease) and study design (diagnostic test accuracy studies [DTAs], observational studies of treatment effect in SeHCAT positive patients, and randomised controlled trial [RCT] of bile acid sequestrants [BAS] treatment in patients without SeHCAT testing). Text summaries were supported by tables and figures as appropriate.

As no studies were found for the assessment of SeHCAT's test accuracy and very few studies for the accuracy of SeHCAT to predict treatment response, it was decided to include studies reporting response to BAS given a positive test to estimate the probability of a positive BAS response at different SeHCAT cut off points. Based on the data retrieved, a random effects meta-analysis was performed to find a pooled estimate for each of the three cut-off values.

Statistical analyses were performed using the following software: RevMan (version 5), Comprehensive Meta-Analyses (CMA version 2), and STATA (STATA™ for Windows, version 10, Stata Corp; College Station, TX).

See Section 4 in the DAR for additional information on assessment of clinical effectiveness.

Cost-effectiveness

Model Structure and Methodology

As no relevant models were identified in the searches, a *de novo* model was developed for each population. This model consists of two parts, a decision model reflecting the diagnostic and initial treatment phase and a Markov model to estimate long term costs and effects. The Assessment Group compares various strategies.

The scoping document clearly defined SeHCAT and no SeHCAT as strategies. The option of Trial of treatment was also mentioned without specifically including it as a comparator. According to the clinical experts at the scoping meeting, Trial of treatment is rarely used as a treatment strategy and was thus not considered relevant. However, Trial of treatment can also not be completely excluded as an option. Thus, in this report the Assessment Group presents two sets of results: one where Trial of treatment is not considered as a comparator and one where it is.

For the diarrhoea-predominant inflammatory bowel disease (IBS-D) population the Assessment Groups compares first the SeHCAT strategy

using 3 different cut-off points (absorption <5%, <10% and <15%) with no SeHCAT testing, i.e., treating patients as IBS-D patients. In the second set of results, Trial of treatment is added as a strategy. For the Crohn's population, the same strategies are included with the exception of SeHCAT 5%, as no data was available for this strategy. In this population, No SeHCAT entails treatment for the chronic diarrhoea (which may or may not be a direct result of a disease relapse).

The models used in the analyses are described in detail. The stochastic analyses are based on cohort simulations. To investigate decision uncertainty, second-order uncertainty micro-simulations were run. All costs and effects were discounted by 3.5%. The model incorporated a lifetime horizon to estimate outcomes in terms of quality-adjusted life years (QALYs) and costs from the perspective of the National Health Service (NHS). Only health effects of patients were included.

See Section 5 in the DAR for more information on cost-effectiveness assessment.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Developing Recommendations

After reviewing the evidence the Diagnostic Advisory Committee (DAC) agrees draft recommendations on the use of the technology in the National Health Service (NHS) in England. When formulating these recommendations, the Committee has discretion to consider those factors it believes are most appropriate to the evaluation. In doing so, the Committee has regard to any relevant provisions of the National Institute for Health and Care Excellence's (NICE's) Directions, set out by the Secretary of State for Health, and legislation on human rights, discrimination and equality. In undertaking evaluations of healthcare technologies, NICE takes into account the broad balance of clinical benefits and costs, the degree of clinical need of patients under consideration, any guidance issued to the NHS by the Secretary of State that is specifically drawn to the attention of NICE by the Secretary of State, and any guidance issued by the Secretary of State, and the potential for long-term benefits to the NHS of innovation.

The Committee takes into account advice from NICE on the approach it should take to making scientific and social value judgements. Advice on social value judgements is informed in part by the work of NICE's Citizens Council.

The Committee takes into account how its judgements have a bearing on distributive justice or legal requirements in relation to human rights, discrimination and equality. Such characteristics include, but are not confined to: race, gender, disability, religion or belief, sexual orientation, gender reassignment and pregnancy or maternity.

The Committee considers the application of other Board-approved NICE methods policies, such as the supplementary guidance on discounting and the end-of-life criteria, if they are relevant to the evaluation.

Because the Programme often evaluates new technologies that have a thin evidence base, in formulating its recommendations the Committee balances the quality and quantity of evidence with the expected value of the technology to the NHS and the public.

The credibility of the guidance produced by NICE depends on the transparency of the DAC's decision-making process. It is crucial that the DAC's decisions are explained clearly, and that the contributions of registered stakeholders and the views of members of the public are considered. The reasoning behind the Committee's recommendations is explained, with reference to the factors that have been taken into account.

The language and style used in the documents produced by the Committee are governed by the following principles:

- Clarity is essential in explaining how the DAC has come to its conclusions.
- The text of the documents does not need to reiterate all the factual information that can be found in the information published alongside the guidance. This needs careful judgement so that enough information and justification is given in the recommendations to enable the reader to understand what evidence the DAC considered and, if appropriate, who provided that evidence.

The Committee may take into account factors that may provide benefits to the NHS or the population, such as patient convenience. It may also consider costs and other positive or negative impacts on the NHS that may not be captured in the reference-case cost analysis, such as improved processes.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Results of Analysis for Diarrhoea-Predominant Irritable Bowel Syndrome (IBS-D)

No information was available to estimate the transition probabilities in the Markov models other than for all-cause mortality. Therefore, a range of scenarios were used to show the impact of the assumptions on the model estimates of health and cost.

In some scenarios, the use of SeHCAT (tauroselcholic [^{75}selenium] acid) was cost effective. In others, it was not cost-effective. The results of the economic evaluation showed that there is considerable uncertainty about the cost-effectiveness of SeHCAT testing for people diagnosed with IBS-D.

An additional analysis was carried out to explore the impact of the cost of additional testing for people whose disease does not respond to IBS-D treatment in all of the scenarios. This additional testing resulted in no change in any of the scenarios in terms of whether SeHCAT testing was found to be cost effective.

Results of Analysis for Crohn's Disease

No information was available to estimate the transition probabilities in the Markov models other than for all-cause mortality. Therefore, a range of scenarios were used to show the impact of the assumptions on the model estimates of health and cost.

Again, in some scenarios, the use of SeHCAT was cost effective. In others, it was not cost effective. The results of the economic evaluation showed that there is considerable uncertainty about the cost-effectiveness of SeHCAT testing for people diagnosed with Crohn's disease who have not had ileal resection.

Considerations

The Committee concluded that, given the apparent prevalence of undiagnosed bile acid malabsorption, there is the potential for patient and system benefit associated with using SeHCAT. But the Committee concluded that there is currently insufficient evidence to determine whether and under what circumstances SeHCAT is a cost-effective option for diagnosing bile acid malabsorption in people with chronic diarrhoea who have been diagnosed with IBS-D or Crohn's disease without ileal resection. The Committee agreed that a programme of research was needed to evaluate this technology, the condition and the effects of treatment, and that its research recommendations would stimulate the collection of evidence about the potentially important clinical benefits and potential harms of using SeHCAT and treating bile acid malabsorption. The Committee felt that, given the cost of the test and the unpleasantness of the treatment, research was essential to establish cost-effectiveness and benefit of SeHCAT for this population, and that the population would be best served by research, including research to address the acceptability of treatment, before the recommendation of widespread adoption of this test.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

The National Institute for Health and Care Excellence (NICE) sends the Diagnostics Assessment Report (DAR), with any confidential material removed, to registered stakeholders for comment. Stakeholders have 10 working days to return comments. Models supporting the DAR are made available to registered stakeholders on request during this period.

NICE presents anonymised registered stakeholder comments on the DAR, along with any responses from NICE or the External Assessment Group (EAG), to the Committee and later publishes these comments on its website.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

The Diagnostics Advisory Committee considered clinical and cost-effectiveness evidence from a systematic review of SeHCAT (tauroselcholic [75 selenium] acid) performed by an External Assessment Group.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

There is uncertainty about whether using SeHCAT reduces the use of other diagnostic tests and clinician visits. Some clinical specialists suggest that placing SeHCAT earlier in the pathway would not stop additional tests such as colonoscopy or flexible sigmoidoscopy being done. Other clinical specialists thought that a positive SeHCAT test earlier in the pathway would result in cost savings because people with chronic diarrhoea would then not have additional tests, which is currently the case.

Potential Harms

False-positive and false-negative results

Qualifying Statements

Qualifying Statements

- This guidance represents the view of the National Institute for Health and Care Excellence (NICE), which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Implementation of the Guideline

Description of Implementation Strategy

The National Institute for Health and Care Excellence (NICE) will support this guidance through a range of activities to promote the recommendations for further research. The research proposed will be passed to the NICE Medical Technologies Evaluation Programme research facilitation team for the development of specific research trial protocols as appropriate. NICE will also incorporate the research recommendations in section 7 of the original guideline document into its guidance research recommendations database (available on the NICE website at www.nice.org.uk) and highlight these recommendations to public research bodies. A costing report will not be developed.

Implementation Tools

Mobile Device Resources

Patient Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). SeHCAT (tauroselcholic [75 selenium] acid) for the investigation of diarrhoea due to bile acid malabsorption in people with diarrhoea-predominant irritable bowel syndrome (IBS-D) or Crohn's disease without ileal resection. London (UK): National Institute for Health and Care Excellence (NICE); 2012 Nov. 34 p. (Diagnostics guidance; no. 7).

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2012 Nov

Guideline Developer(s)

National Institute for Health and Care Excellence (NICE) - National Government Agency [Non-U.S.]

Source(s) of Funding

National Institute for Health and Care Excellence (NICE)

Guideline Committee

Diagnostics Advisory Committee

Composition of Group That Authored the Guideline

Standing Committee Members: Dr Trevor Cole, Consultant Clinical Geneticist, Birmingham Women's Hospital Foundation Trust; Dr Paul Collinson, Consultant Chemical Pathologist, St George's Hospital; Professor Ian Cree, Senior Clinical Advisor, NIHR Evaluation Trials and Studies Coordinating Centre, University of Southampton; Professor Erika Denton, National Clinical Director for Imaging, Department of Health; Dr Simon Fleming, Consultant in Clinical Biochemistry and Metabolic Medicine, Royal Cornwall Hospital; Professor Elizabeth (Lisa) Hall, Professor of Analytical Biotechnology, Institute of Biotechnology, Department of Chemical Engineering and Biotechnology, University of Cambridge; Professor Chris Hyde, Professor of Public Health and Clinical Epidemiology, Peninsula College of Medicine and Dentistry; Professor Noor Kalsheker, Professor of Clinical Chemistry, Molecular Medical Sciences, University of Nottingham; Dr Mark Kroese, Consultant in Public Health Medicine, PHG Foundation and UK Genetic Testing Network; Professor Adrian Newland (*Chair*), Consultant Haematologist, Barts and the London NHS Trust; Dr Richard Nicholas, Consultant Neurologist, Heatherwood and Wexham Park Hospital, Imperial Healthcare Trust; Ms Margaret Ogden, Lay member; Dr Diego Ossa, Director Market Access Europe, Novartis Molecular Diagnostics; Mr Stuart Saw, Director of Finance and Procurement, Tower Hamlets Primary Care Trust; Professor Mark Sculpher, Professor of Health Economics, Centre for Health Economics, University of York; Dr Steve Thomas, Senior Lecturer and Consultant Radiologist, University of Sheffield; Mr Paul Weinberger, CEO, Diasolve Ltd, London; Mr Christopher Wiltsher, Lay member

Specialist Committee Members: Dr Kevin Bradley, Consultant in Nuclear Medicine & Radiology, Oxford Radcliffe Hospitals; Dr Matthew Brookes, Consultant Gastroenterologist, Royal Wolverhampton NHS; Dr Annelies Maenhout, Consultant in Nuclear Medicine, Chelsea and Westminster NHS Foundation Trust and Royal Brompton and Harefield NHS Trust; Professor John McLaughlin, Consultant Gastroenterologist, Salford Royal Hospitals NHS Foundation Trust; Dr Nick Read, Chair and Medical Advisor, IBS Network; Dr Richard Thompson, Senior Lecturer in Paediatric Hepatology, Institute of Liver Studies, King's College London

Financial Disclosures/Conflicts of Interest

Committee members are required to submit a declaration of interests on appointment, in every year of their tenure, and at each Committee meeting, in line with the National Institute for Health and Care Excellence's (NICE's) code of practice for declaring and dealing with conflicts of interest.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site . Also available for download as a Kindle or EPUB ebook from the NICE Web site .

Availability of Companion Documents

The following are available:

- Riemsma R, Al MJ, Corro Ramos I, Deshpande S, Armstrong N, Lee Y-C, Ryder S, Noake C, Krol M, Oppe M, Kleijnen J, Severens JL. SeHCAT (tauroselcholic [^{75}selenium] acid) for the investigation of bile acid malabsorption (BAM) and measurement of bile acid pool loss: A systematic review and cost-effectiveness analysis. Diagnostics assessment report. York (UK): Kleijnen Systematic Reviews Ltd; 2012. 264 p. Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site .
- Diagnostics Assessment Programme manual. London (UK): National Institute for Health and Care Excellence; 2011 Dec. 130 p. Electronic copies: Available from the NICE Web site .

Patient Resources

The following is available:

- SeHCAT (tauroselcholic [75 selenium] acid) for the investigation of diarrhoea due to bile acid malabsorption in people with diarrhoea-predominant irritable bowel syndrome (IBS-D) or Crohn's disease without ileal resection. Information for the public. London (UK): National Institute for Health and Care Excellence (NICE); 2012 Nov. (Diagnostics guidance; no. 7). Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

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